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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,769	12/29/2000	Judith K. Gwathmey	JGT-002	5078

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EXAMINER
SAUNDERS, DAVID A

ART UNIT	PAPER NUMBER
1644	10

DATE MAILED: 05/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
751,769	GWATHMEY
Examiner	**Group Art Unit**
SAUNDERS	1647

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 2/19/03.

☑ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1-8, 10-12, 30-32 is/are pending in the application.

Of the above claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☑ Claim(s) 1-8, 10-12, 30-32 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Interview Summary, PTO-413

☐ Notice of Informal Patent Application, PTO-152

☐ Other _____

Office Action Summary

The amendment of 2.19/03 has been entered; claims 1-8, 10-12 and 30-32 are pending and under examination.

Applicant's urgings have overcome the previously stated objection to claim 5 under 37 CFR 1.75 (c).

Applicant's amendment has overcome previously stated rejections under 35 U.S.C. 112, 102 and 103.

Applicant's amendment has necessitated the following new grounds of rejection.

Claims 1-8, 10-17 and 30-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is unclear as to where the cardiac protein(s) are -- within the liposome, or at its surface?

Claim 31 is likewise unclear as to where the carbohydrate receptor is located.

Claims 1-8, 10-12 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Amended claim 1 and new claims 30 and 31 recite new matter.

Claim 1 recites new matter because the disclosure has nowhere disclosed the use a cardiac protein per se as a targeting moiety of the liposome. To the contrary, the disclosure only

teaches antibodies directed to a cardiac protein as a targeting moiety of the liposome (page 4, lines 34-35 and page 7, lines 7-8). Disclosure of the use of an antibody directed to a specific type of antigen does not support use of the antigen, per se, as a targeting moiety.

New claim 30 recites new matter because the Markush group members "actin" and tropomyosin" were not recited in there original disclosure. The examiner finds these mentioned no where at pages 4 or 7.

New claim 31 recites new matter because the disclosure teaches no use of a "carbohydrate receptor" on liposomes as a targeting moiety. To the contrary, the disclosure teaches that the carbohydrate receptors or on the cells to be targeted, not on the liposomes (page 14, lines 12-20). The targeting moiety on the liposomes would be a carbohydrate (specifically limited to galactose or mannose, as disclosed at page 4, line 36 and page 14, line 20), not a carbohydrate receptor. Disclosure of use of a carbohydrate does not support use of a "carbohydrate receptor" as a targeting moiety.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8, 10-17 and 30-32 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

As noted supra, in the 112 new matter rejection, applicant has failed to liposomes with a cardiac protein as a targeting moiety. One of skill would fail to see how a liposome bearing a cardiac protein would be targeted to a cell also having cardiac proteins, because there is no moiety that would link the liposomal to the cellular cardiac protein. Further applicant has not taught any utility for providing both cardiac proteins and antibodies thereto as components of the liposome. Likewise, applicant has failed to teach liposomes with a carbohydrate receptor as a targeting moiety to a cell also having a carbohydrate receptor, because there would be no moiety that would link the liposomal to the cellular carbohydrate receptor.

Claims 1-8, 10-17 and 30-32 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Torchilin et al. (5,534,241).

Torchilin et al. teach liposomes bearing polychelating moieties with a lipophilic tail portion embedded in a lipid bilayer and hydrophilic chelating moieties facing the surrounding aqueous medium. Taught chelating moieties (col. 5, lines 4-19) include chelating agents contemplated by applicant (e.g. as in original claim 3). Torchilin et al. teach that the liposome surface can also bear a targeting moiety/group (col. 9, lines

18+), which can specifically be a lectin (col. 9, line 37). Any lectin is inherently a "carbohydrate receptor." Thus every element of claim 31 is shown.

Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Unger et al. (5,585,112).

Unger et al. teach liposomes that can contain chelated iron (col. 37, lines 33-51) they also teach that the liposome can have a lectin (Carbohydrate receptor) as a targeting moiety (col. 25, lines 26 and 35). Thus all features of claim 31 are shown.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr

May 12, 2003

David A Saunders

DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644